

## **REMARKS/ARGUMENTS**

In response to the Office Communication mailed April 3, 2007, Applicants' submit the following Remarks in conjunction with the above Amendment.

### **CLAIM OBJECTIONS**

Each of the Examiner's objections have been addressed. The claims have been amended to provide antecedent basis, remove terms such as "approximately" and "substantially", and to change "inch" to "inches".

### **REJECTIONS UNDER 35 USC 112**

In the past, application of a body fluid sample to a reagent portion of a test strip involved lancing a bodily fluid sample location with a lancing device that is entirely separate from a meter. Following the lancing, the conventional lancing device would be set aside, and a conventional meter having a test strip inserted into a test strip slot therein would be brought to the bodily fluid sample location for receiving the body fluid sample. Advantageously, Applicants' invention, as set forth at claim 21 and its dependents, as now amended, permits lancing with a lancet and withdrawal thereof with a lancet drive including a spring. Then, a test strip is moved by a motor to the bodily fluid sample location without moving the housing relative to the bodily fluid sample location, making the process easier for a user. The rejection is thereby overcome.

### **REJECTIONS UNDER 35 USC 101**

Claim 29 has been amended and no longer recites "a patient's skin", and the rejection is overcome.

## REJECTIONS UNDER 35 USC 102

Claims 21-24 and 26-35 are rejected as being anticipated by Anderson et al. (US 5,279,294). As amended, Claim 21 requires that after lancing and withdrawing of the lancing device, the test strip is movable to a bodily fluid sample contacting position within 0.010 inch of said center of said bodily fluid sample. This is advantageous because Applicants' test strip is best positioned at or near the center of the body fluid sample for receiving a high percentage of available body fluid sample. This is important, because it is desired to be able to test with only a small amount of body fluid sample, such as may be available at an alternative site other than fingertips and/or using a thinner and less painful needle.

The Examiner is referred to Figure 4 of Anderson et al. which shows a reagent pad 72 offset from a lancet hole 70. Thus, the reagent pad 72 of Anderson et al. does not come to rest at the center of the bodily fluid sample which would be at the center of the lancet hole 70. Anderson et al. have a reagent pad 72 that is positioned next to the lancet hole 70 prior to lancing. In the system of Anderson et al., a bodily fluid sample is expected to flow sufficiently outward from the lancing site to be applied to the reagent 72 even though the reagent pad is not centered at or near the lancing site. This means that a large volume of sample must flow from the lancing site in order for a test to yield results. This is a disadvantage, because as mentioned, it is desired to be able to test with only a small amount of body fluid sample, such as may be available at an alternative site other than fingertips and/or using a thinner and less painful needle.

Therefore, claim 21 is allowable, and claims 22-35 are allowable as being dependent therefrom.

In addition, Claim 27, as amended, recites that the body fluid sample has a submicroliter volume, and new claim 52 requires a 1/3 microliter volume. It is

submitted that these would very likely provide an insufficient amount of sample for the apparatus of Anderson et al. to perform a reliable test. Claims 27 and 52 are thus allowable for this additional reason.

In addition, claim 28, as amended, requires that when the test strip is in the bodily fluid sample-contacting position, a fill channel of the test strip is aligned with the bodily fluid sample within 0.005 inches of said center of said bodily fluid sample. This feature is not disclosed by Anderson et al., and thus claim 28 is allowable for this additional reason. Moreover, new claims 53-56, require that the body fluid sample has a diameter of 0.005 inches. It is further submitted that would very likely provide an insufficient amount of sample for the apparatus of Anderson et al. to perform a reliable test. Claims 28 and 53-56 are thus allowable for these additional reasons.

#### REJECTIONS UNDER 35 USC 103

Claim 25 is rejected as being unpatentable over Anderson et al. (US 5,279,294) in view of Yuzhakov et al (US 2003/0028125). Claim 25 is allowable as being dependent from claim 21 for the reason set forth above indicating that Anderson et al. does not teach or suggest all of the features of Applicants' claim 21, and nor does any combination with Yuzhakov et al.

#### NEW CLAIMS 52-56

New claims 52-56 are allowable as being dependent upon amended claim 21, and for the additional reasons set forth above, i.e., as each reciting a feature not taught or suggested by Anderson et al. nor Yuzhakov et al.

Appl. No. 10/701,993  
Amendment dated June 21, 2007  
Amendment and Reply to Office Action mailed April 3, 2007

The Commissioner is authorized to charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. 50-2019. A duplicate page is enclosed.

Respectfully submitted,

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Dated: June 21, 2007

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